

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-90 (cancelled)

91. (currently amended) A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) mixing an edible water-soluble polymer component, water and an active component comprising drug particles to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by mixing;

(c) forming a wet film from said deaerated matrix by coating or casting the film;

(d) providing a surface having top and bottom sides;

(e) feeding said film onto said top side of said surface; and

(f) drying said film within about 10 minutes or fewer,

wherein said drying step further comprises:

(i) rapidly forming a visco-elastic film having said drug particles uniformly distributed throughout within about the first 4.0 minutes by applying hot air currents at temperatures of about 60°C to about 100°C to said bottom side of said surface with substantially no top air flow to prevent flow migration and intermolecular forces from creating aggregates or conglomerates of said drug particles thereby maintaining the compositional uniform distribution of components; and

(g) (ii) further drying said visco-elastic film to form a self-supporting edible film having drug particles uniformly distributed throughout.

92. (cancelled)

93. (previously presented) The process according to claim 91, wherein said active component is taste masked.

94. (previously presented) The process according to claim 91, wherein said wet film has a thickness of at least about 30 μ m.

95. (previously presented) The process according to claim 91, wherein said wet film has a thickness of at least about 500 μ m.

96. (previously presented) The process according to claim 91, wherein said wet film has a viscosity of about 400 cps to about 100,000 cps.

97. (previously presented) The process according to claim 91, further comprising the step of removing said self-supporting film from said surface.

98. (previously presented) The process according to claim 97, further comprising the step of dividing said self-supporting film into individual dosage forms of substantially equal dimensions.

99. (previously presented) The process according to claim 98, further comprising the step of packaging each of said individual dosage forms.

100. (previously presented) The process according to claim 91, wherein said self-supporting film is formed in conjunction with a removable backing.

101. (currently amended) A process for making a self-supporting, edible film dosage unit having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component comprising

drug particles and water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by mixing to prevent cavitation of the matrix in a manner which pulls air into the matrix;

(c) forming a wet film from said deaerated wet matrix by coating or casting the film;

(d) drying said film within about 10 minutes or fewer,

wherein said drying step further comprises:

(i) rapidly forming a visco-elastic film having said drug particles uniformly distributed throughout within about the first 4.0 minutes by applying hot air currents at temperatures of about 60°C to about 100°C to said film to prevent flow migration and intermolecular forces from creating aggregates or conglomerates of said drug particles thereby maintaining the compositional uniform distribution of components; and

(~~e~~) (ii) further drying said visco-elastic film to form a self-supporting edible film having drug particles uniformly distributed throughout; and

(~~f~~)(e) dividing said self-supporting film into dosage forms of substantially equal dimensions, wherein each of said dosage forms is compositionally equal.

102. (previously presented) The process according to claim 101, wherein each of said dosage forms has substantially the same mass.

103. (previously presented) The process according to claim 101, wherein each of said dosage forms has substantially the same thickness.

104. (currently amended) A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component ~~selected from the group consisting of pharmaceutical actives, cosmetic actives and combinations thereof~~

comprising drug particles and water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by mixing to prevent cavitation of the matrix, thereby reducing formation of air bubbles;

(c) forming a wet film from said deaerated wet matrix by coating or casting the film, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; and

(d) drying said film within about 10 minutes or fewer,
wherein said drying step further comprises:

(i) rapidly forming a visco-elastic film having said drug particles uniformly distributed throughout within about the first 4.0 minutes by applying hot air currents at temperatures of about 60°C to about 100°C to said film to prevent flow migration and intermolecular forces from creating aggregates or conglomerates of said drug particles thereby maintaining the compositional uniform distribution of components; and

(e) (ii) further drying said visco-elastic film to form a self-supporting edible film having drug particles uniformly distributed throughout, said dried film having a uniform distribution of said polymer and said solvent components, a uniform weight and a uniform thickness.

105. (cancelled)

106. (currently amended) A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component comprising drug particles and water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by mixing;

(c) forming a wet film from said deaerated wet matrix within a time period before the active degrades by coating or casting the film, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; and

(d) drying said film within about 10 minutes or fewer,
wherein said drying step further comprises:

(i) rapidly forming a visco-elastic film having said drug particles uniformly distributed throughout within about the first 4.0 minutes by applying hot air currents at temperatures of about 60°C to about 100°C to said film to initiate drying of the depth of said film prior to forming a polymer skin on said top surface of said film and to prevent flow migration and intermolecular forces from creating aggregates or conglomerates of said drug particles thereby maintaining the compositional uniform distribution of components; and

~~(e)~~ (ii) further drying said visco-elastic film to form a self-supporting edible film having drug particles uniformly distributed throughout, said dried film having a uniform distribution of said polymer and said solvent components, a uniform weight and a uniform thickness.

107. (cancelled)

108. (currently amended) A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component comprising drug particles and water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by mixing to reduce formation of air bubbles;

(c) forming a wet edible film from said deaerated wet matrix by coating or casting the film, said film having a top surface and a bottom surface; and

(d) drying said film within about 10 minutes or fewer,
wherein said drying step further comprises:

(i) rapidly forming a visco-elastic film having said drug particles uniformly distributed throughout within about the first 4.0 minutes by applying hot air currents at temperatures of about 60°C to about 100°C to said film, wherein said air currents are applied to said bottom surface of said film at a velocity greater than to said top surface of said film to prevent flow migration and intermolecular forces from creating aggregates or conglomerates of said drug particles thereby maintaining the compositional uniform distribution of components; and

~~(e)~~ (ii) further drying said visco-elastic film to form a self-supporting edible film having drug particles uniformly distributed throughout.

109. (previously presented) The process according to claim 108, wherein said air currents applied to said top surface of said film are less than that which cause surface rippling or skinning prior to drying of the depth of said film.

110. (currently amended) A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, a pharmaceutical active component comprising drug particles and water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by mixing;

(c) forming a wet edible film from said deaerated wet matrix by coating or casting the film, said film having a top surface, a bottom surface and a depth of at least about 500µm between said top and bottom surfaces; and

(d) drying said film within about 10 minutes or fewer,
wherein said drying step further comprises:

(i) rapidly forming a visco-elastic film having said drug particles uniformly distributed throughout within about the first 4.0 minutes by applying hot air currents at temperatures of about 60°C to about 100°C to said film, wherein said air currents are less than that which cause surface rippling or skinning prior to drying of the depth of said film, to prevent flow migration

and intermolecular forces from creating aggregates or conglomerates of said drug particles thereby maintaining the compositional uniform distribution of components; and

(e) (ii) further drying said visco-elastic film to form a self-supporting edible film having drug particles uniformly distributed throughout.

111. (currently amended) A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component comprising drug particles and water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by mixing;

(c) forming a wet edible film from said deaerated wet matrix by coating or casting the film, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; and

(d) drying said film within about 10 minutes or fewer,
wherein said drying step further comprises:

(i) rapidly forming a visco-elastic film having said drug particles uniformly distributed throughout within about the first 4.0 minutes by applying hot air currents at temperatures of about 60°C to about 100°C to said film to prevent flow migration and intermolecular forces from creating aggregates or conglomerates of said drug particles thereby maintaining the compositional uniform distribution of components; and

(e) (ii) further drying said visco-elastic film, wherein said dried film is self-supporting and has drug particles uniformly distributed throughout and said top surface of said dried film is non-rippled.

112. (currently amended) A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) combining and mixing an edible water-soluble polymer component, an active component comprising drug particles and water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by mixing to reduce air bubble inclusions and applying a vacuum;

(c) forming an edible film from said deaerated matrix by coating or casting the film, said film having a top surface and a bottom surface; and

(d) drying said film within about 10 minutes or fewer,
wherein said drying step further comprises:

(i) drying said film from said bottom surface to said top surface by applying hot air currents at temperatures of about 60°C to about 100°C to said bottom surface of said film until a visco-elastic film having said drug particles uniformly distributed throughout is achieved within about the first 4.0 minutes; and

(e) (ii) further drying said visco-elastic film to form a self-supporting edible film having drug particles uniformly distributed throughout.

113. (cancelled)

114. (currently amended) A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component comprising drug particles and water to form an edible matrix with a compositionally uniform distribution of components;

(b) deaerating said matrix by mixing;

(c) forming a wet edible film from said deaerated wet matrix by coating or casting the film, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; and

(d) drying said film within about 10 minutes or fewer,

wherein said drying step further comprises:

(i) rapidly forming a visco-elastic film having said drug particles uniformly distributed throughout within about the first 4.0 minutes by applying hot air currents at temperatures of about 60°C to about 100°C to said film, wherein said air currents are insufficient to cause one or more of the following:

- (i) surface skinning prior to drying the depth of said film;
- (ii) surface rippling;
- (iii) self-aggregation of components;
- (iv) non-uniformity in the thickness of said film; and
- (v) non-uniformity of mass per unit volume; and

(e) (ii) further drying said visco-elastic film to form a self-supporting edible film having drug particles uniformly distributed throughout.

115. (cancelled)

116. (currently amended) A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

- (a) combining and mixing an edible water-soluble polymer component, an edible active component comprising drug particles and water to form an edible matrix with a compositionally uniform distribution of components;
- (b) adding an anti-foaming agent to release oxygen from said mixture of components;
- (c) further deaerating said matrix by mixing;
- (d) forming a wet edible film from said deaerated matrix by coating or casting the film;
- (e) providing a surface having top and bottom sides;
- (f) feeding said wet film onto said top side of said surface; and
- (g) drying said film within about 10 minutes or fewer,

wherein said drying step further comprises:

(i) rapidly forming a visco-elastic film having said drug particles uniformly distributed throughout within about the first 4.0 minutes by directing hot air currents at temperatures of about 60°C to about 100°C at said bottom side of said surface to prevent air flow migration and intermolecular forces from creating aggregates or conglomerates of said drug particles thereby maintaining the compositional uniform distribution of components; and

~~(h)~~ (ii) further drying said visco-elastic film to form a self-supporting edible film having drug particles uniformly distributed throughout.

117. (currently amended) A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) forming a masterbatch premix of an edible water-soluble polymer component and water;

(b) deaerating said premix by mixing;

(c) feeding a predetermined amount of said deaerated premix via a first metering pump and a control valve to at least one of a first mixer and a second mixer;

(d) adding an active component comprising drug particles that degrade with prolonged exposure to water to said at least one of said first and second mixers;

(e) mixing said active component and said predetermined amount of said premix to form a matrix having a uniform distribution of components;

(f) feeding an amount of said matrix to a pan through at least one second metering pump;

(g) forming a wet film from said matrix within a time period before the active degrades by coating or casting the film with one or more rollers;

~~(g)~~(h) providing a surface having top and bottom sides;

~~(h)~~(i) feeding said film onto said top side of said surface;

~~(i)~~(j) drying said film within about 10 minutes or fewer,

wherein said drying step further comprises:

(i) rapidly forming a visco-elastic film having said drug particles uniformly distributed throughout within about the first 4.0 minutes by applying hot air currents at temperatures of

about 60°C to about 100°C to said bottom side of said surface with substantially no top air flow to prevent air flow migration and intermolecular forces from creating aggregates or conglomerates of said drug particles thereby maintaining the compositional uniform distribution of components; and

- (j) (ii) further drying said visco-elastic film to form a self-supporting edible film having drug particles uniformly distributed throughout; and
- (k) removing said self-supporting film from said surface.

118-119. (cancelled)